

In the Examiner's view the phrase "in a single step" is not supported by the specification as the disclosure does not appear to describe or suggest coating a substrate surface with an actinic radiation curable single fluid aqueous composition, then irradiating or exposing such surface in a single step. Applicants point out, however, that the disclosure does indeed describe irradiating or exposing a substrate surface coated with Applicants' composition in a single step. In support of Applicants' assertion, the Examiner is directed to page 11, lines 9-11 of Applicants' disclosure which states that "once the aqueous coating composition is applied to the substrate surface, it is *immediately* cured without any prior removal, using either high energy electrons or UV radiation." (emphasis added). Therefore, according to the literal teachings of Applicants' disclosure, the substrate surface is irradiated immediately once coated with Applicants' composition to effect complete curing of the composition on the substrate's surface. The irradiation is only done once so that the surface is irradiated or exposed "in a single step". To clarify the fact that no additional curing steps are needed in Applicants' method, the curing or irradiating the surface step in claim 1 is now characterized as "efficiently irradiating the surface in a single step."

Applicants respectfully request the Examiner to withdraw the objection.

Further, Applicants were informed by the Examiner, in an Office Interview of June 13, 2001, that the Examiner would seriously reconsider the "finality" of the Office Action since adoption of the phrase "in a single step" was suggested and discussed with Applicants during that interview. Reconsideration and withdrawal of the "Final Rejection" is hereby requested.

(4-5) Rejection Under 35 U.S.C. 112, First Paragraph

Claims 1- 49 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In particular, the Examiner opines that the recitation “in a single step” in claims 1 and 48 and the recitation “once” in claim 27 were not supported by disclosure at the time it was filed. It is noted that use of the term “once” has been amended and now reads “in a single step”.

As discussed in the preceding paragraphs, related to the objection under 35 U.S.C. 132, Applicants are of the position that the phrase “in a single step”, used in Claims 1, 27, and 48, is indeed supported in Applicants’ disclosure. Applicants amended claims therefore describe subject matter already disclosed in the specification and describes it in such a way as to reasonably convey to one skilled in the art that the inventors did have possession of the claimed invention at the time the application was filed. In view of the foregoing, Applicants respectfully request the Examiner to withdraw the rejection.

The Invention

Firstly, the invention is an improved actinic radiation curable **single fluid aqueous composition** having a water soluble compound containing (a) at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group and (b) water; wherein the improvement is when a surface is coated with the composition and exposed in a **single step** to actinic radiation in the

presence of the water, a cured film is formed, wherein **less than 50 ppb** of uncured residue is extractable therefrom when the film is immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Secondly, the invention is a **method for producing a low-extractable film** comprising the steps of:

- (a) providing an actinic radiation curable aqueous single fluid composition having a water soluble compound containing (a) at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group and water;
- (b) applying said aqueous composition onto a surface; and
- (c) **efficiently** irradiating the surface in a **single step** with actinic radiation in the presence of the water;

thereby forming a cured film is formed wherein **less than 50 ppb** of uncured residue is extractable therefrom when the film is immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

(6-7) Rejection Under 35 U.S.C. 102

Claims 1-19, 27-42 and 49-50 have been rejected under 35 U.S.C. 102 (b) as being anticipated by Buethe et al. (U.S. Patent 4,287,039). The Examiner opines that Buethe et al. disclose a radiation curable aqueous composition comprising water and a radiation curable compound containing at least one alpha, beta ethylenically unsaturated radiation polymerizable group, such as a polyglycidyl ether of a polyhydric alcohol and other acrylates. The composition can be applied to a substrate such as a plastic, paper, or metal, and irradiated with actinic radiation such as ultraviolet or electron beam radiation in a single step, to form a cured coated substrate for use in coating foodstuff containers due to their low toxicity in comparison to

conventional radiation curable finishes, which are toxicologically unsafe because of their monomer residue content.

Buethe et al. do not anticipate Applicants invention as they disclose aqueous binder **dispersions** made up of water and one or more prepolymers dispersed in the water (see Col. 1, lines 62-68). The prepolymer in Buethe et al. contains polymerizable carbon double bonds and is selected from polyvinylpyrrolidone and a copolymer of vinylpropionate or vinylacetate with vinylpyrrolidone. As an aqueous **dispersion**, the prepolymers employed in the Buethe et al compositions are not **water soluble**. In addition, the Buethe et al requires a dispersant in order to disperse the prepolymer in the water (see Col. 2, lines 1-6).

By contrast, Applicants' have invented a **single fluid aqueous composition** containing a "water soluble compound " or polymerizable group that forms a homogeneous phase or single fluid with the water of the composition. Consequently, Applicants' composition is not a dispersion nor does it form a dispersion or require a dispersant to disperse the water soluble compound (i.e. polymerizable group) in the water.

As for the meaning of the phrase "single fluid" used by Applicants in describing their aqueous composition, it is intended to mean a composition that is both "non-emulsion and non-colloidal." This definition was established by the Patent Office during the prosecution of USSN 08/614,587, now issued U.S. Patent 5,725,646 (see enclosed Paper No. 6, Interview Summary for USSN 08/614,587, dated August 21, 1997) and is being adopted by Applicants in the present prosecution. In view of the definition adopted by Applicants', it is clear that Applicants' **single fluid** aqueous compositions are not similar to an aqueous dispersion such as that described by Buethe et al.

The Examiner also believes that the Buethe et al. coating, once cured, would “inherently” have less than 50 ppb of uncured extractable residue therefrom. Applicants respectfully point out that while the cured composition in Buethe et al. could conceivably be used to coat foodstuff containers or in food packaging, this alone does not establish support sufficient to indicate that the amount of uncured migratable or extractable residue in the cured Buethe et al. coating would have less than 50 ppb of extractables as required by the FDA for materials to be used in direct food contact applications. Such an inherency is no way supported or suggested anywhere by Buethe et al. On the other hand, when a substrate surface is coated with Applicants single fluid aqueous composition and cured upon immediately exposing the surface in a single step to actinic radiation, in the presence of the water, less than 50 ppb of uncured residue is extractable from the film when the film is immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Applicants’ single fluid aqueous composition is completely different and patentably distinct from the aqueous dispersions described in Buethe et al. As such, Buethe et al. do not anticipate Applicants’ single fluid aqueous composition. Applicants kindly ask that the rejection be withdrawn.

(8-10) Rejection Under 35 U.S.C. 102

Claims 1-19, 27-42, 44 and 48 have been rejected under 35 U.S.C. 102(e) as being anticipated by Reich et al. (US Patent 6,011,078). The Examiner opines that Reich et al. discloses an aqueous radiation curable coating composition made up of a **blend** of a water soluble radiation curable compound having an α,β -ethylenically unsaturated radiation polymerizable double bond (S) and a **water dispersible** radiation curable compound having

an α,β -ethylenically unsaturated radiation polymerizable double bond (P) (see Col. 4, lines 13-63 and Col. 2, lines 44-56).

The Reich et al. composition can be applied to a substrate and irradiated with ultraviolet light or electron beam radiation. However, since, the Reich et al. composition is a dispersion they do not anticipate Applicants' **single fluid aqueous composition** wherein the water soluble compound (i.e. polymerizable group) forms a homogeneous phase or single fluid with the water. Applicants' composition is not a dispersion nor does it form a dispersion or require a dispersant in order to disperse the polymer.

The Examiner also believes that the Reich et al. coating, once cured would "inherently" have less than 50 ppb of uncured extractable residue therefrom. Applicants respectfully point out that while the cured compositions in Reich et al. could conceivably be used to coat foodstuff containers or in food packaging, this alone does not establish enough support to indicate that the amount of uncured migratable or extractable residue in a cured film of the Reich et al. coating would have less than 50 ppb of extractables as required by the FDA for materials to be used in direct food-contact applications. Such an inherency is no way supported or suggested anywhere by Reich et al. On the other hand, when a substrate surface is coated with Applicants single fluid aqueous composition and cured upon immediately exposing the surface in a single step to actinic radiation, in the presence of the water, less than 50 ppb of uncured residue is extractable from the film when the film is immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Applicants' single fluid aqueous composition is completely different and patentably distinct from the aqueous dispersions described in Reich et

al. As such, Reich et al. do not anticipate Applicants' single fluid aqueous composition. Applicants kindly ask that the rejection be withdrawn.

(11) Rejection Under 35 U.S.C. § 103

Claims 20-26 and 43-47 have been rejected as being unpatentable over Buethe et al. As for the rejection, the Examiner opines that Buethe et al. teaches Applicants' invention, even though it specifically does not teach the use of polymer, metal and paper substrates. Furthermore, the Examiner avers that the amount of extractables recited in Applicants' claims are well known in the food packaging art, and hence, it would have been obvious to one of ordinary skill in the art to use any standard measuring process to determine the extractable amount for health related reasons when coating a substrate (i.e. food container) with Buethe et al.'s materials.

Applicants submit that Buethe et al. do not teach or even suggest Applicants' invention. As discussed above regarding the Examiner's rejection under 35 U.S.C. Section 103, Buethe et al. teach aqueous **dispersions** and require the use of **dispersants** to disperse the polymer in the water. This is not equivalent to Applicants' **single fluid** aqueous composition where no dispersion is formed.

Furthermore, Buethe et al. teach away from Applicants' invention in that the compositions in Buethe et al. contain water insoluble or dispersible components and incorporate colloids and emulsifiers. These components are in direct contrast to what is required in Applicants' composition which contains water soluble and single fluid (i.e. non-emulsion and non-colloidal) compatible materials.

As for the extractable content of Applicants cured composition and the method of measuring same, Applicants agree with the Examiner. It is

well known to determine extractable amounts using standard measurement protocols. However, the Examiner goes further to conclude that it would have therefore been obvious for one skilled in the art to use these standard measurement protocols to determine the amount of extractables allowable for health related reasons. Applicants agree with the Examiner in part on this point as it is important to note that while a coating composition of the type prepared in Buethe et al. can be used to “treat food containers”, such use does not necessarily constitute a coating which could be used in direct food contact applications. Coatings used in direct food contact applications **must** meet minimum governmental regulations, for example, established by the Food and Drug Administration (“FDA”) in the United States. While the Examiner’s assertion that protocols for measuring extractable levels of materials useful in food packaging is correct, the compositions of Buethe et al. do not in fact meet such requirements, namely wherein:

“a cured film produced from the composition would have less than 50 ppb of uncured residue extractable therefrom when immersed and heated in 10 ml of a simulant liquid per square inch of cured film”

Only cured compositions meeting the above standards qualify for direct food contact use in food packaging applications. However, these physical standards for the cured film are not taught or even suggested in curing the Buethe et al. composition. A cured film, meeting these attributes is taught solely Applicants. Buethe et al. simply mention that their aqueous compositions “can conceivably be used for coating foodstuff containers.” However, such disclosure is vacant of any suggestion, proof or illustration, that the compositions, once cured, are regulatory compliant for use in direct food contact applications.

Furthermore, as aqueous dispersions, the Buethe et al. compositions once cured would not be regulatory compliant since as a cured aqueous dispersion, it would have an residue extractable level greater than 50 ppb. Scientifically speaking, this is because, as a dispersion, Buethe et al. teach two phase compositions wherein water removal is necessary to coalesce the dispersed phase and form a continuous film. Also, upon removal of the water, the cure of the film would be inhibited by oxygen and the mobility of the cross-linkable monomeric or oligomeric groups would be inhibited resulting in a polymeric mixture having a high viscosity and molecular weight. For example, Buethe et al. teach a compositional viscosity of no less than 600 cp, preferably 1000 cp, and a molecular weight of no less than 350 and more preferably no less than 600. Accordingly, a coating made from the Buethe et al. composition would cure poorly on the surface (oxygen inhibition) and be low in the necessary mobility required for efficient polymerization. As a result, the cured film would not meet the FDA's requirements for direct food contact films.

Additionally, aqueous dispersions typically employ large amounts of stabilizers, surfactants and other additives as components. These components result in cured films having high levels of extractables due to the presence of the additives as they do not react and form part of the polymer network. Residual levels due to these components can, for example, be as high as 1000 to 10,000 ppm (1,000,000 ppb to 10,000,000 ppb) based on adding 0.1 to 1% of an emulsifier. This in turn would result in a cured film having an residue extractable substantially higher than the 50 ppb requirement of the FDA. In Buethe et al. the level of emulsifier alone is between 3 and 12 wt.%. Accordingly, the cured composition of Buethe et al.

would not and does not meet FDA regulatory standards, i.e. less than 50 ppb of extractable residue. By contrast, Applicants provide ample data to support the fact that their films formed from the single fluid aqueous compositions are in no doubt compliant with FDA direct food contact regulations (see in particular pages 12 to 22 and Examples 8, 9, 10 and 11 of Applicants specification). In view of the foregoing, Applicants kindly ask that the rejection be withdrawn.

(12) Rejection Under 35 U.S.C. § 103

Claims 10, 43-44, and 50 have been rejected as being unpatentable over Reich et al. As for the rejection, the Examiner opines that Reich et al. teaches Applicants' invention, even though it specifically does not teach the use of polymer, metal and paper substrates. Furthermore, the Examiner avers that the amount of extractables recited in Applicants' claims are well known in the food packaging art, and hence, it would have been obvious to one of ordinary skill in the art to use any standard measuring process to determine the extractable amount for health related reasons when coating a substrate (i.e. food container) with the Reich et al. materials.

Applicants submit that Reich et al. do not teach or even suggest Applicants' invention. As discussed above regarding the Examiner's rejection under 35 U.S.C. Section 103, Reich et al. teach aqueous **dispersions** and require the use of **dispersants** to disperse the polymer in the water. This is not equivalent to Applicants' **single fluid** aqueous composition where no dispersion is formed.

Furthermore, Reich et al. teach away from Applicants' invention in that the compositions in Reich et al. contain water insoluble or dispersible

components and incorporate colloids and emulsifiers. These components are in direct contrast to what is required in Applicants' composition which contains water soluble and single fluid (i.e. non-emulsion and non-colloidal) compatible materials.

As for the extractable content of Applicants cured composition and the method of measuring same, Applicants agree with the Examiner. It is well known to determine extractable amounts using standard measurement protocols. However, the Examiner further concludes that it would have therefore been obvious for one skilled in the art to use these standard measurement protocols to determine the amount of extractables allowable for health related reasons. Applicants agree with the Examiner in part on this point, as it is important to note that while a coating composition of the type prepared in Reich et al. can be used to "treat food containers", such use does not necessarily constitute a coating which could be used in direct food contact applications. Coatings used in direct food contact applications **must** meet minimum governmental regulations, for example, established by the Food and Drug Administration ("FDA") in the United States. While the Examiner's assertion that protocols for measuring extractable levels of materials useful in food packaging is correct, the compositions of Reich et al. do not in fact meet the necessary governmental requirements mentioned above. These standards are not taught or even suggested by curing the Reich et al. composition. Cured films meeting these attributes are taught solely by Applicants. Reich et al. simply mention that their aqueous compositions "can conceivably be used for coating foodstuff containers." However, such disclosure is vacant of any suggestion, proof or illustration, that the compositions, once cured, are regulatory compliant for use in direct food contact applications.

Furthermore, as aqueous dispersions, the Reich et al. compositions once cured would not be regulatory compliant since as a cured aqueous dispersion, it would have an residue extractable level greater than 50 ppb because it is a two phase composition. In addition, water removal would be necessary to coalesce the dispersed phase and form a continuous film. Also, upon removal of the water, the cure of the film would be inhibited by oxygen and the mobility of the cross-linkable monomeric or oligomeric groups would be inhibited resulting in a polymeric mixture having a high viscosity and molecular weight. As a result, the cured film would not meet FDA requirements.

Additionally, aqueous dispersions typically employ large amounts of stabilizers, surfactants and other additives as components. These components result in cured films having high levels of extractables due to the presence of the additives as they do not react and form part of the polymer network. Residual levels for these components can, for example, be as high as 1000 to 10,000 ppm (1,000,000 ppb to 10,000,000 ppb) based on adding 0.1 to 1% of an emulsifier. This in turn would result in a cured film having an residue extractable level substantially higher than the 50 ppb requirement of the FDA. Accordingly, the cured composition of Reich et al. does not meet the FDA regulatory standards, i.e. less than 50 ppb of extractable residue. By contrast, Applicants provide ample data to support the fact that their films formed from the single fluid aqueous composition are compliant with FDA direct food contact regulations (see in particular pages 12 to 22 and Examples 8, 9, 10 and 11 of Applicants specification). In view of the foregoing, Applicants kindly ask that the rejection be withdrawn.

(13) Rejection of Claims Under 35 U.S.C. § 103

Claims 17-26, 43-47 and 50 have been rejected as being unpatentable in view of Reich et al. in further view of Buethe et al.

The Examiner opines that the combined teachings of Reich et al. in view of Buethe et al. teach Applicants' invention, even though they specifically do not teach the use of polymer, metal and paper substrates. Furthermore, the Examiner avers that the amount of extractables recited in Applicants claims are well known in the food packaging art, and hence, it would have been obvious to one of ordinary skill in the art to use any standard measuring process to determine the extractable amount for health related reasons when coating a substrate (i.e. food container) under the combined teachings of Reich et al. and Buethe et al.

Applicants submit that the combination of Reich et al. and Buethe et al does not teach or even suggest Applicants' invention. As discussed above regarding the Examiner's rejection under 35 U.S.C. Section 103, both Reich et al. and Buethe et al. teach aqueous **dispersions** and require the use of **dispersants** to disperse the polymer in the water. This is not equivalent to Applicants' **single fluid** aqueous composition wherein no dispersion is formed.

Furthermore, both references teach away from Applicants' invention in that the compositions contain water insoluble or dispersible components and incorporate colloids and emulsifiers. These components are in direct contrast to what is required in Applicants' composition which contains a water soluble compound that forms a single fluid (i.e. non-emulsion and non-colloidal) with the water.

As for the extractable content of Applicants cured composition and the method of measuring same, Applicants agree with the Examiner. It is well known to determine extractable levels using standard measurement protocols. Yet, going further, the Examiner concludes that it would have therefore been obvious for one skilled in the art to use these standard measurement protocols to determine the amount of extractables allowable for health related reasons. Applicants agree with the Examiner in part on this point, as it is important to note that a coating composition prepared pursuant to the individual or combined teachings of Reich et al. and Buethel et al. may be used to “treat food containers”, however, such use does not necessarily constitute a coating which could be used in direct food contact applications. Coatings used in direct food contact applications **must** meet minimum governmental regulations established, for example, by the Food and Drug Administration (“FDA”) in the United States. While the Examiner’s assertion that protocols for measuring extractable levels of materials to be used in food packaging is correct, the compositions of these references in combined or alone would not in fact meet the FDA direct food contact requirements outlined above. These standards are not taught or even suggested for the cured compositions of the references. Cured films meeting these attributes are taught solely by Applicants. Reich et al. and Buethel et al. simply mention or suggest aqueous compositions that “can conceivably be used for coating foodstuff containers.” However, such disclosure is vacant of any suggestion, proof or illustration, that the compositions, once cured, are or would be regulatory compliant for use in direct food contact applications.

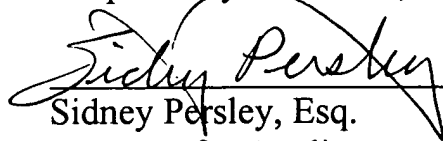
Furthermore, as aqueous dispersions, the combination teaches compositions that, once cured, would not be and are not regulatory

complaint since as a cured aqueous dispersion, they would have an residue extractable level substantially greater than 50 ppb since the dispersion are two phase compositions. In addition, they teach that water removal is necessary to coalesce the dispersed phase and form a continuous film. Also, upon removal of the water, the cure of the film would be inhibited by oxygen and the mobility of the cross-linkable monomeric or oligomeric groups would be inhibited resulting in a polymeric mixture of high viscosity and molecular weight. As a result, the cured film would not meet FDA requirements.

Additionally, aqueous dispersions typically employ large amounts of stabilizers, surfactants and other additives as components. These components would result in a cured film having high levels of extractables due to the presence of the additives as they do not react and form part of the polymer network. Residual levels for these components can, for example, be as high as 1000 to 10,000 ppm (1,000,000 ppb to 10,000,000 ppb) based on adding 0.1 to 1% of an emulsifier. This results in cured films having residue extractable levels substantially higher than the FDA required 50 ppb level. Accordingly, the combined teachings of these references would not and do not produce cured films or coatings that meet FDA regulatory standards, i.e. less than 50 ppb of extractable residue. On the other hand, Applicants provide ample data to support the fact that their films formed from the single fluid aqueous compositions are compliant with FDA direct food contact regulations (see in particular pages 12 to 22 and Examples 8, 9, 10 and 11 of Applicants specification). In view of the foregoing, Applicants kindly ask that the rejection be withdrawn.

Applicants believe that the amendments and remarks provided herein adequately and completely address the rejections raised by the Examiner. Therefore, Applicants respectfully request allowance and issuance of the outstanding claims.

Respectfully submitted,


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Date 5/20/02

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

The paragraph at **page 3, lines 8-16**, has been amended as follows:

-- A further embodiment of this invention is an improved actinic radiation curable single fluid aqueous composition comprising a water soluble compound which contains at least one α , β -ethylenically unsaturated, radiation polymerizable group; and water; wherein the improvement comprises the requirement that when a surface is coated with the composition and exposed [once] in a single step to actinic radiation in the presence of the water, a cured film is formed wherein less than 50 ppb of uncured residue is extractable from the cured film when immersed and heated in 10 ml of a simulant liquid per square inch of cured film. Preferably, the water soluble compound is a water soluble oligomer containing two or more acrylic groups. --

In the Claims

Claim 1 has been amended as follows:

1. (Twice Amended) A method for producing a low-extractable film comprising the steps of:

(a) providing an actinic radiation curable single fluid aqueous

composition comprising

(i) a water soluble compound which contains at least one α , β -ethylenically unsaturated, actinic radiation polymerizable group and (ii) water;

(b) applying said aqueous composition onto a surface; and

(c) efficiently irradiating the surface in a single step with actinic radiation in the presence of the water; thereby forming a cured film wherein less than 50 ppb of uncured residue is extractable from the cured film when immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Claim 27 has been amended as follows:

27 . (Twice Amended) An improved actinic radiation curable [aqueous] single fluid aqueous composition comprising: a water soluble compound which contains (a) at least one α , β -ethylenically unsaturated, radiation polymerizable group and (b) water; wherein the improvement comprises that when a surface is coated with the composition and exposed [once] in a single step to actinic radiation in the presence of the water, a cured film is formed wherein less than 50 ppb of uncured residue is extractable therefrom when immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Claim 51 has been added as follows:

51. (New) A method for providing a packaging material constructed from a low-extractable film having a content of less than 50 ppb of extractable uncured film residue per square inch when the packaging material is immersed and heated in 10 ml of simulant liquid, comprising:

(a) providing an actinic radiation curable single fluid aqueous composition comprising

- (i) a water soluble compound which contains at least one α , β - ethylenically unsaturated, actinic radiation polymerizable group and (ii) water;
- (b) applying said aqueous composition onto a surface of said packaging material; and
- (c) efficiently irradiating the surface in a single step with actinic radiation in the presence of the water.

Claim 52 has been added as follows:

52. (New) The method according to claim 51, wherein the packaging material is selected from the group consisting of food packaging, beverage packaging, pharmaceutical packaging, medical packaging, and health care packaging materials.